

**SECTION 5**  
**510(k) SUMMARY (Cont.)****JUL 18 2013****510(k) Notification K 131046**

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**GENERAL INFORMATION****Applicant:**

Venous Health Systems, Inc.  
3270 Alpine Road  
Portola Valley, CA 94028  
U.S.A  
Phone: 650-646-3327  
Fax: 650-854-4772

**Contact Person:**

Rich Laguna  
Director Quality Assurance & Operations  
eMail: Rlaguna@venoushealth.com  
Phone: 650-646-3327 extension 225  
Fax: 650-854-4722

**Date Prepared:** February 24, 2013

**DEVICE INFORMATION**

The Vasculaire Compression System ("Vasculaire System") is a mobile, intermittent pneumatic compression system intended to provide sequential compression therapy to the lower limb(s) in the clinical setting or home environment. The Controller is battery powered, provides selectable compression cycles and system monitoring of the compression therapy. The Sleeves are provided in a foot & calf or a calf only configuration for selectable lower limb(s) compression therapy.

**Classification:**

Compressible Limb Sleeve, 21 CFR§870.5800

**Product Code:**

JOW

**Trade Name:**

VASCULAIRE COMPRESSION SYSTEM ("Vasculaire System")  
VASCULAIRE SLEEVE (FOOT & CALF)  
VASCULAIRE SLEEVE (CALF)

**Generic/Common Name:**

Compressible Limb Sleeve

**SECTION 5****510(k) SUMMARY (Cont.)**

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**PREDICATE DEVICE(S)**

Venous Health Systems, Inc., / Vasculaire Compression System (K122609)  
Covidien / Kendall SCD™ 700 Sequential Compression (K120944)

**INDICATIONS FOR USE**

The Vasculaire Compression System is a mobile, intermittent pneumatic compression system intended to provide sequential compression therapy to the lower limb(s) in the clinical setting or home environment.

The Vasculaire Compression System is indicated for use in:

- Preventing deep vein thrombosis (DVT)
- Enhancing blood circulation
- Diminishing post-operative pain and swelling
- Reducing wound healing time
- Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers
- Treatment of chronic venous insufficiency
- Reducing edema

**PRODUCT DESCRIPTION**

The Vasculaire Compression System is a mobile, intermittent pneumatic compression system intended to provide compression therapy to the lower limb(s) in the clinical setting or home environment. The Vasculaire Compression System includes three components: the Controller, the Sleeve and the Charger.

The Sleeve is a multiple-cell bladder intended to be attached directly to the lower limb(s). It is intended to provide compression to the tissue surrounding the vasculature. The Sleeve is provided in two configurations. The first configuration is a foot and calf Sleeve that provides sequential compression to the foot and calf. The second configuration is a calf only Sleeve that provides sequential compression to the calf. The Controller is connected to the Sleeve using two flange ports and can be mounted directly onto the Sleeve for a fully mobile system. The flange ports allow the air from the Controller to effect compression on the foot and calf zones independently. The Controller allows the user to select between foot and calf compression or a calf only compression. The Controller also allows the user to select compression cycles of approximately one to three cycles per minute. The Controller is a lightweight (less than 1 lb.), battery-powered, electromechanical control unit intended to provide and monitor the inflation cycle for enhanced circulation therapy. The Charger consists of a medical grade power supply and the table top docking station.

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**SUBSTANTIAL EQUIVALENCE**

The indications for use for the Vasculaire Compression System are equivalent to the indications for use for the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the Vasculaire System is substantially equivalent to the predicate devices.

**TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION**

There is no FDA performance standard required for the Vasculaire Compression System. All necessary testing was conducted on the modified Vasculaire System to support determination of substantial equivalence to the predicate devices. The testing performed included:

- ISO 14971:2007 Medical Devices-Application of Risk Management to Medical Devices / Home Use & Design Risk analysis
- BS EN ISO 10993-1:2009, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing and the FDA Guidance Document entitled, “Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices (G95-1)”
- ANSI/AAMI/IEC 62366:2007 Medical devices – Application of usability engineering to medical devices / Human Factors and Usability validation for the usability of the Vasculaire Compression System in the home environment

**Vasculaire Compression System substantiation for Home Use**

- Use Hazard(s) Identification – Manufacturers and User Facility Device Experience (MAUDE) review and market surveillance search
- Home use hazard(s) mitigation through design

MDR Identified Hazards	Design Mitigation
Tethered trips & falls	Elimination of external air tubing and controller attached power cords.
Tethered limited range of movement	
Tubing induced skin injury	

- Home Use/User Failure Modes Effects Analysis (HUFMEA)
- Home Usability Validation Study

**SUMMARY**

The Vasculaire Compression System is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - W066-G609  
Silver Spring, MD 20993-0002

July 18, 2013

Venous Health Systems, Inc.  
Rich Laguna  
3270 Alpine Road  
Portola Valley, CA 94028

Re: K131046

Trade/Device Name: Vasculaire Compression System  
Regulation Number: 21 CFR 870.5800  
Regulation Name: Compressible Limb Sleeve  
Regulatory Class: II  
Product Code: JOW  
Dated: June 19, 2013  
Received: June 19, 2013

Dear Mr. Laguna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram Zuckerman", written over a faint, dotted rectangular background.

for Bram Zuckerman, MD  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**SECTION 4**  
**INDICATIONS FOR USE STATEMENT**

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510(k) Number (if known): K131046

Device Name: Vasculaire Compression System

**Indications For Use:**

The Vasculaire Compression System is a mobile, intermittent pneumatic compression system intended to provide sequential compression therapy to the lower limb(s) in the clinical setting or home environment.

The Vasculaire Compression System is indicated for use in:

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- Treatment of chronic venous insufficiency
- Reducing edema

Prescription Use  X   
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use \_\_\_\_\_  
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*M. L. Killian*